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PATENT
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Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

By: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Roberto L. Rivera

Application No.: Unassigned

Filed: Herewith

For: Delivery System to Modulate
Immune Response

Examiner: Unassigned

Art Unit: Unassigned

PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE SPECIFICATION:

On page 1, after the title of the invention, and before the first paragraph entitled "FIELD OF THE INVENTION," please insert the following paragraphs:

-- COPYRIGHT NOTICE

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reproduction by anyone of the patent document or the patent disclosure as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of, and claims the benefit of priority from, co-pending U.S. Patent Application Serial No 09/041,514, filed March 12, 1998, the full disclosures of which are incorporated herein by reference in their entirety for all purposes.--

IN THE CLAIMS:

Please cancel claims 1-30. Please amend claim 31, and add new claims 34-44 as follows. A marked-up version of all pending claims is shown in the attached Appendix.

31. (Amended) A composition adapted to induce an immune response comprising an enteric coating and an immunogen bound to an inert particle, said inert particle having a mesh size greater than 35 mesh.

--34. (New) The composition of claim 31 wherein said immunogen is selected from the group consisting of a peptide, a protein fragment, a protein, a gene, a gene fragment, a DNA, an RNA and combinations thereof.

35. (New) The composition of claim 31 wherein said immunogen is a vaccine.

36. (New) The composition of claim 33, wherein the potentiating agent is bound to the inert particle, and the inert particle is selected from the group consisting of an immunogen-bound inert particle and a non-immunogen bound inert particle.

37. (New) The composition of claim 31 which induces an increase in the number of T lymphocytes.

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38. (New) The composition of claim 37 which induces an increase in a cell population selected from the group consisting of a TH1 lymphocyte, a cytotoxic T lymphocyte (CTL), and combinations thereof.

39. (New) The composition of claim 31 wherein said inert particle has a mesh size greater than about 40 mesh.

40. (New) The composition of claim 31 where said immunogen is bound to an inert particle selected from the group consisting of a nonpareil, a silica powder, a salt crystal and a sugar crystal.

41. (New) A composition adapted to induce an immune response comprising an enteric coating and an immunogen bound to an inert particle, said inert particle having a mesh size greater than about 40 mesh.

42. (New) The composition of claim 41 further comprising a potentiating agent bound to an inert particle, wherein the inert particle is selected from the group consisting of an immunogen-bound inert particle and a non-immunogen bound inert particle.

43. (New) The composition of claim 41 wherein the immune response comprises an increase in a T lymphocyte population.

44. (New) The composition of claim 43 wherein the immune response comprises an increase in a cell population selected from the group consisting of a TH1 lymphocyte, a cytotoxic T lymphocyte (CTL), and combinations thereof.--

REMARKS

The subject application is a divisional of U.S. Patent Application Serial No 09/041,514, filed March 12, 1998. It is noted that claims 31-33 were withdrawn from consideration in the parent application as a result of the restriction requirement mailed from the U.S. Patent and Trademark Office on June 22, 1999. This preliminary amendment is made to cancel claims 1-30 and add new claims 34-45, in addition to inserting in the specification a copyright notice pursuant to 37 CFR § 1.71(e) and to perfecting the priority data in the specification.

Also, with entry of this amendment, claim 31 has been amended, and new claims 34-44 have been added. Claim 31 has been amended to improve clarity. New claims 34-40 depend from claim 31 and incorporate elements from original claims 4-6 and 9-12, respectively. New independent claim 41 parallels claim 31 but recite a mesh size of greater than about 40 mesh. The original claim 25 provides additional support for claim 41. New claims 42-44 depend from claim 41 and respectively recite elements from original claims 26, 29, and 30. Additional support for these new claims is provided throughout the specification.

Applicants further note that the claim amendment and addition of new claims have been made to improve clarity of claim language and to more clearly point out and distinctly claim Applicant's invention. No new matter has been introduced by the preliminary amendment.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400 x 5209.

Respectfully submitted,



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Appendix Marked-up version of all pending claims

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Marked-up Version of All Pending Claims

31. (Amended) A composition adapted to induce an immune response comprising an enteric coating and an immunogen [contained on] bound to an inert particle [and having an enteric coating], said inert particle having a mesh size greater than [about] 35 mesh.

32. (As originally filed) The composition of claim 31 contained in a gel capsule.

33. (As originally filed) The composition of claim 31 further comprising a potentiating agent.

34. (New) The composition of claim 31 wherein said immunogen is selected from the group consisting of a peptide, a protein fragment, a protein, a gene, a gene fragment, a DNA, an RNA and combinations thereof.

35. (New) The composition of claim 31 wherein said immunogen is a vaccine.

36. (New) The composition of claim 33, wherein the potentiating agent is bound to the inert particle, and the inert particle is selected from the group consisting of an immunogen-bound inert particle and a non-immunogen bound inert particle.

37. (New) The composition of claim 31 which induces an increase in the number of T lymphocytes.

38. (New) The composition of claim 37 which induces an increase in a cell population selected from the group consisting of a TH1 lymphocyte, a cytotoxic T lymphocyte (CTL), and combinations thereof.

39. (New) The composition of claim 31 wherein said inert particle has a mesh size greater than about 40 mesh.

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40. (New) The composition of claim 31 where said immunogen is bound to an inert particle selected from the group consisting of a nonpareil, a silica powder, a salt crystal and a sugar crystal.

41. (New) A composition adapted to induce an immune response comprising an enteric coating and an immunogen bound to an inert particle, said inert particle having a mesh size greater than about 40 mesh.

42. (New) The composition of claim 41 further comprising a potentiating agent bound to an inert particle, wherein the inert particle is selected from the group consisting of an immunogen-bound inert particle and a non-immunogen bound inert particle.

43. (New) The composition of claim 41 wherein the immune response comprises an increase in a T lymphocyte population.

44. (New) The composition of claim 43 wherein the immune response comprises an increase in a cell population selected from the group consisting of a TH1 lymphocyte, a cytotoxic T lymphocyte (CTL), and combinations thereof.

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